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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/477,983 06/07/95 RUBIN

J 40399/321/N1

EXAMINER

13N2/0805

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ART. UNIT ID. PAPER NUMBER

16

1901  
DATE MAILED:

08/05/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☐ Claim(s) 13-14, 23-24, 29, 36-37, 39, 40-43 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 13-14, 23-24, 29, 36-37, 39, 41-43 is/are rejected.
- ☒ Claim(s) 40 is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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## **DETAILED ACTION**

### ***Response to Arguments***

1. Several amendments have been filed in the instant application (filed 21 October 1996, 15 January 1997, 12 March 1997, 23 May 1997 and 22 May 1997. The pending claims are now 13-14, 23-24, 29, 36-37 and 39-43 in the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 21 October 1996 have been fully considered but they are not deemed to be persuasive (Applicant merely stated that the amendments were to avoid double patenting rejections in copending Application 08/455,620).

### ***Response to Amendment***

#### ***Specification***

5. A substitute specification has been requested in related applications to the instant application because of the numerous amendments which needed to be made to the specification.

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Applicant's have provided a substitute specification on two separate occasions (15 January 1997 and 12 March 1997) yet the latest substitute specification also includes 6 more pages of amendments. As stated in the related applications, the numerous amendments which have been submitted result in a specification with potential errors as well as a copy which is not easily readable for the printer (at the time of allowance and issue). In addition, the filing of a substitute specification requires the submission of a hand corrected copy of the portions of the original specification which are being added or deleted with additions being underlined and deletions being bracketed. In addition, a statement that the substitute specification contains no new matter and that the substitute specification includes the same changes as are indicated in the hand corrected original specification is required. Such statement must be a verified statement if made by a person not registered to practice before the Office. See MPEP § 714.20. Applicant must also request entry of the substitute specification.

6. Applicant's inclusion and update of the history of the parent application (in the amendment filed 15 January 1997) which the instant application claims priority is appreciated. However, since the substitute specification and the amendments thereto were not entered, the required substitute specification should include this information along with all of the other amendments which have been submitted up to 23 May 1997.

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***Claim Objections***

7. Claim 40 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. See MPEP § 608.01(n). For example, the claim could recite "the polypeptide of any one of claims 23, 24, 29, 36 and 37" or "the polypeptide of claim 23, 24, 29, 36 or 37". Accordingly, the claim has not been further treated on the merits. Applicant should also note that there is no antecedent basis for "the polypeptide" in claim 23 from which the instant claim depends (however, since the claim has not been further treated on the merits, this rejection is not being made at this time).

***Double Patenting***

8. Claims 13-14, 23, 29, 36-37, 39, 41-43 of this application conflict with at least claims 28, 30-31, 39, 41, 43-44 and 51 of Application No. 08/455,620. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention,"

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in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 13-14, 23, 29, 36-37, 39, 41-43 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 28, 30-31, 39, 41, 43-44 and 51 of copending Application No. 08/455,620. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

#### ***Claim Rejections - 35 USC § 112***

11. Claims 39 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for KGF and KGF polypeptides which is truncated within the region of amino acids 32-78, does not reasonably provide enablement for "portions thereof" as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope.

The specification teaches a keratinocyte growth factor (KGF) of 194 amino acids in length and DNA encoding said KGF. The specification also teaches that the first 31 amino acids are a signal sequence that is cleaved in the mature protein and that amino acids 32-78 confer epithelial cell specificity to the protein. However, the specification does not provide support for any portion of a KGF polypeptide, having ***preferential mitogenic activity on cells of epithelial***

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*origin.* Two separate issues are raised by the wording of the claim. First, the language of a portion of a KGF polypeptide having preferential mitogenic activity does not give any structure to the amino acid sequence which is necessary for this preferential activity. This would include any fragment amino acids which stimulate preferential mitogenic activity. There is no support in the specification that any portion from KGF would encode the preferential mitogenic activity of a KGF polypeptide, and it would required undue experimentation to determine how the amino acids could be arranged in order to facilitate preferential mitogenic activity. Furthermore, the claim must recite sufficient elements necessary for enablement of the claimed invention. In the instant case, there is evidence in the specification that amino acids 32-78 are *responsible* for conferring mitogenic specificity to the protein, the specification does not teach which other portions are necessary for mitogenic activity on epithelial cells or that portions of KGF which do not include these amino acids would possess preferential mitogenic activity for epithelial cells. Therefore, it would require undue experimentation for one of ordinary skill in the art to determine which portions of KGF would confer preferential mitogenic activity for epithelial cells, absent clear and convincing evidence to the contrary.

### *Conclusion*

12. No claim is allowed.

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13. The claims of the instant application and those of copending application 08/455,620 were previously directed to inventions which were obvious over one another. However, the inventions of the instant application and copending application 08/455,620 are now directed to the same invention, thus precipitating the new ground of rejection (provisional statutory double patenting).

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 8AM to 4PM. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

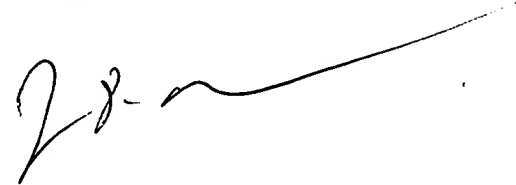
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [stephen.walsh@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.  
July 29, 1997

(A)



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800